JUN 29 2005

K051069

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BIOMET

510(k) Summary

Applicant/Sponsor:

Arthrotek. Inc.
(A wholly owned subsidiary of Biomet, Inc.)
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581-0587

Contact Person:

Gary Baker
Biomet Manufacturing Corp.
P.O. Box 587
Warsaw, Indiana 46581-0587
Phone: (574) 267-6639
FAX: (574) 372-1683

Proprietary Name: Nonresorbable CentraLoc™ Tibial Screw and Washer

Common Name: Tibial screw and washer

Classification Name: Fastener, Fixation, Nondegradable, Soft Tissue. (21 CFR §888.3040)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

LactoSorb® Tibial L-15 Screw and Washer – Arthrotek Inc. (K033233)
No Profile LactoSorb® L-15 Screw and Washer – Arthrotek Inc. (K021832)
STALIF TT – Surgicraft Ltd. (K041617)

Device Description: The Nonresorbable CentraLoc™ Tibial Screws and Washers are a series of tibial screws and washers designed for soft tissue fixation to bone.

Intended Use:

The tibial screws and washers are indicated for the following procedures:

1. Anterior cruciate ligament (ACL) and posterior cruciate ligament (PCL) reconstruction
2. Medial collateral ligament repair
3. Lateral collateral ligament repair

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P.O. Box 587
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56 E. Bell Drive
Warsaw, IN 46582

OFFICE 574.267.6639 ■ FAX 574.267.8137 ■ E-MAIL biomet@biomet.com

4. Posterior oblique ligament repair
5. Iliotibial band tenodesis reconstruction
6. Patellar ligament and tendon repair

This device is also intended to be used as back-up fixation in ACL reconstruction in conjunction with other marketed devices in order to provide additional fixation strength in instances of questionable bone quality.

Summary of Technologies: The Nonresorbable CentraLoc™ Tibial Screws and Washers have the same intended use and indications for use as the predicate Lactosorb® Tibial L-15 Screw and Washer and No Profile Lactosorb® L-15 Screw and Washer devices. The mechanical design is similar to the predicate resorbable devices.

Non-Clinical Testing: Mechanical testing found the Nonresorbable CentraLoc™ Tibial Screw and Washer to be substantially equivalent to the predicate No Profile Lactosorb® L-15 Screw and Washer devices for the uses intended.

Clinical Testing: Clinical testing was not necessary to determine substantial equivalence for the Nonresorbable CentraLoc™ Tibial Screw and Washer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 29 2005

Arthrotek, Inc.
C/o Mr. Gary Baker
Biomet Manufacturing Corporation
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K051069
Trade/Device Name: Nonresorbable CentraLoc™ Tibial Screw and Washer
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: MBI, HWC
Dated: April 25, 2005
Received: April 26, 2005

Dear Mr. Baker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-__. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

10(k) Number (if known): K051069

Device Name: Nonresorbable CentraLoc™ Tibial Screw and Washer

Indications For Use:

1. Anterior cruciate ligament (ACL) and posterior cruciate ligament (PCL) reconstruction
2. Medial collateral ligament repair
3. Lateral collateral ligament repair
4. Posterior oblique ligament repair
5. Iliotibial band tenodesis reconstruction
6. Patellar ligament and tendon repair

This device is also intended to be used as back-up fixation in ACL reconstruction in conjunction with other marketed devices in order to provide additional fixation strength in instances of questionable bone quality.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K051069